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June 8, 1999

Docket No. 99D-0557 Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Dear Sirs/Madams:

It was wise to propose a ban on transplants from non-human primates because of the significant infectious disease risk. However, it is extremely unwise to now consider pigs as the primary source for xenotransplants, because of the over 25 diseases in pigs that can infect humans. One is the new Malavsian Nipah virus that has devasted humans and pigs alike. Porcine Endogenous Retroviruses have infected human cells in vitro. Also, it was a violation of the national Environmental Policy Act to fail to perform an environmental impact statement before allowing clinical xenotransplantation experiments.

There are safer, more cost-effective and humane alternatives to these animal transplants that are not being considered by those in authority. We need to invest in preventive medicine to reduce the need for transplants of all kinds. We need to increase the pool of human donor organs as many European countries have successfully done.

Who will pay for breeding, housing, feeding, medicating, screening, transporting, rendering, and disposing of the waste and remains of herds of transgenic pigs? (Especially when the EPA is wisely placing new restrictions on livestock pollution.)

Xenograft recipients and their close contacts would require life-long monitoring for signs of infection. Your proposed multi-million dollar registry and archive to house blood and tissue from source animals and patients for at least 50 years would be at taxpayer expense. This is outrageous and extremely unfair. And who will be held accountable if a deadly zoonotic virus spreads to the human population?

I do not want my tax dollars used to develop xenotransplantation. The Department of Health and Human Services should ban xenotransplantation from all nonhuman animals immediately. Sincerely, Aura Baullaco

99D-0557

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SOBEST COOCS IN III